



December 2013

QMS15-A

Assessments: Laboratory Internal Audit Program; Approved Guideline

This document provides guidance for how a laboratory can establish an internal audit program to enhance the quality of its services through continual improvement. Whereas an audit program defines the “who,” “what,” “when,” “where,” and “how” of meeting requirements for internal auditing, the audit process describes the details of how to conduct individual laboratory internal audits.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

Clinical and Laboratory Standards Institute

Setting the standard for quality in clinical laboratory testing around the world.

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing clinical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

Consensus Process

Consensus—the substantial agreement by materially affected, competent, and interested parties—is core to the development of all CLSI documents. It does not always connote unanimous agreement, but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and accept the resulting agreement.

Commenting on Documents

CLSI documents undergo periodic evaluation and modification to keep pace with advancements in technologies, procedures, methods, and protocols affecting the laboratory or health care.

CLSI's consensus process depends on experts who volunteer to serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate.

Comments on published CLSI documents are equally essential, and may be submitted by anyone, at any time, on any document. All comments are addressed according to the consensus process by a committee of experts.

Appeals Process

If it is believed that an objection has not been adequately addressed, the process for appeals is documented in the CLSI Standards Development Policies and Process document.

All comments and responses submitted on draft and published documents are retained on file at CLSI and are available upon request.

Get Involved—Volunteer!

Do you use CLSI documents in your workplace? Do you see room for improvement? Would you like to get involved in the revision process? Or maybe you see a need to develop a new document for an emerging technology? CLSI wants to hear from you. We are always looking for volunteers. By donating your time and talents to improve the standards that affect your own work, you will play an active role in improving public health across the globe.

For further information on committee participation or to submit comments, contact CLSI.

Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: 610.688.0100
F: 610.688.0700
www.clsi.org
standard@clsi.org

ISBN 1-56238-895-9 (Print)
ISBN 1-56238-896-7 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

QMS15-A
Vol. 33 No. 15

Volume 33 Number 15

Assessments: Laboratory Internal Audit Program; Approved Guideline

Jennifer Schiffgens, MBA, MT(ASCP), CLS
Beverly McAllister, MS, MT(ASCP)SC
Kathy Chambers, ART
Christopher Grimes
John R. Harbour, MD, FCAP
Nora L. Hess, MBA, MT(ASCP), PMP

Nichole Martin, MSQA, CQA, CMQ/OE, CQIA(ASQ)
Laura McClannan, MS, MT(ASCP)SBB
Lisa A. Selhorst, BS, MT(AMT)
Peggy J. Stupca, MS, CLSp(CG)
Janette Wassung

Abstract

Clinical and Laboratory Standards Institute document QMS15-A—*Assessments: Laboratory Internal Audit Program; Approved Guideline* provides recommendations for establishing an internal audit program and related processes for enhanced quality and continual improvement in the laboratory. The audit program defines the “who,” “what,” “when,” “where,” and “how” of the laboratory’s intent to audit its work, whereas the audit process describes how the act of tracing samples and records through laboratory workflow processes can identify areas of noncompliance and opportunities for improvement. Committed laboratory leadership and individuals willing to share their expertise and experience will enable a successful internal audit program.

Clinical and Laboratory Standards Institute (CLSI). *Assessments: Laboratory Internal Audit Program; Approved Guideline*. CLSI document QMS15-A (ISBN 1-56238-895-9 [Print]; ISBN 1-56238-896-7 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2013.

The Clinical and Laboratory Standards Institute consensus process, which is the mechanism for moving a document through two or more levels of review by the health care community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI documents. Current editions are listed in the CLSI catalog and posted on our website at www.clsi.org.

If you or your organization is not a member and would like to become one, and to request a copy of the catalog, contact us at:

P: 610.688.0100 **F:** 610.688.0700 **E:** customerservice@clsi.org **W:** www.clsi.org



Copyright ©2013 Clinical and Laboratory Standards Institute. Except as stated below, any reproduction of content from a CLSI copyrighted standard, guideline, companion product, or other material requires express written consent from CLSI. All rights reserved. Interested parties may send permission requests to permissions@clsi.org.

CLSI hereby grants permission to each individual member or purchaser to make a single reproduction of this publication for use in its laboratory procedure manual at a single site. To request permission to use this publication in any other manner, e-mail permissions@clsi.org.

Suggested Citation

CLSI. *Assessments: Laboratory Internal Audit Program; Approved Guideline*. CLSI document QMS15-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

Approved Guideline

December 2013

ISBN 1-56238-895-9 (Print)

ISBN 1-56238-896-7 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

.....

Committee Membership

Consensus Committee on Quality Systems and Laboratory Practices

**Carl D. Mottram, BA, RRT, RPFT,
FAARC
Chairholder
Mayo Clinic
Rochester, Minnesota, USA**

**Devery Howerton, PhD, MS,
MT(ASCP)SI
Vice-Chairholder
Centers for Disease Control and
Prevention
Atlanta, Georgia, USA**

Deirdre Astin, MS, MT(ASCP)
New York State Department of Health
Albany, New York, USA

Michael B. Cohen, MD
ARUP Laboratories
Salt Lake City, Utah, USA

Nancy Dubrowny, MS, MT(ASCP)SC
BD Preanalytical Systems
Franklin Lakes, New Jersey, USA

Dennis J. Ernst, MT(ASCP)
Center for Phlebotomy Education
Corydon, Indiana, USA

Michelle Jenkins, MS, MT(AMT) ASQ,
CQE, CMQ/OE
Abbott Diagnostics
Irving, Texas, USA

Michelle McLean, MS, MT(ASCP)
Greiner Bio-One North America, Inc.
Raleigh, North Carolina, USA

Jennifer Schiffgens, MBA, MT(ASCP),
CLS
California Pacific Medical Center
San Francisco, California, USA

Tonya Wilbon, BS, M(ASCP)
FDA Center for Devices and
Radiological Health
Rockville, Maryland, USA

Subcommittee on Quality Management Systems

**Lucia M. Berte, MA, MT(ASCP)SBB,
DLM; CMQOE(ASQ)CSSBB
Chairholder
Laboratories Made Better!
Broomfield, Colorado, USA**

**Tania Motschman, MS, MT(ASCP)SBB,
CQA(ASQ)
Vice-Chairholder
Laboratory Corporation of America
Burlington, North Carolina, USA**

Joan M. Carlson, MLT(CMLTA),
BSc(MLS)
Alberta Health Services – Edmonton
General Hospital
Edmonton, Alberta, Canada

Anne T. Daley, MS, MT(ASCP)DLM,
CMQOE(ASQ)CSSBB
Chi Solutions, Inc.
Ann Arbor, Michigan, USA

Karen Heaton, MLT(CMLTA)
Calgary Laboratory Services
Calgary, Alberta, Canada

Debra Kuehl, MS, M(ASCP)
Centers for Disease Control and
Prevention
Atlanta, Georgia, USA

Elizabeth Sheppard, MBA, HT(ASCP)
Ventana Medical Systems, Inc.
Tucson, Arizona, USA

Melissa Singer, MT(ASCP)
Centers for Medicare & Medicaid
Services
Baltimore, Maryland, USA

Miki Van Houten, MT(ASCP)
Oregon State Public Health Laboratory
Hillsboro, Oregon, USA

Ginger Wooster, MBA, MT(ASCP)
Orchard Software
Milwaukee, Wisconsin, USA

Document Development Committee on Quality Management System: Laboratory Internal Audit Program

Jennifer Schiffgens, MBA, MT(ASCP), CLS Chairholder California Pacific Medical Center San Francisco, California, USA	Nora L. Hess, MBA, MT(ASCP), PMP Chi Solutions, Inc. Sarasota, Florida, USA	Staff Clinical and Laboratory Standards Institute Wayne, Pennsylvania, USA
Beverly McAllister, MS, MT(ASCP)SC Committee Secretary Ephrata Community Hospital Ephrata, Pennsylvania, USA	Nichole Martin, MSQA, COA, CMQ/OE, CQIA(ASQ) Expression Analysis – A Quintiles Company Durham, North Carolina, USA	Luann Ochs, MS <i>Senior Vice President – Operations</i> Jennifer K. Adams, MT(ASCP), MSHA <i>Staff Liaison</i>
Kathy Chambers, ART Surrey, British Columbia, Canada	Laura McClannan, MS, MT(ASCP)SBB Laboratory Corporation of America Burlington, North Carolina, USA	Megan L. Tertel, MA <i>Editor</i>
Christopher Grimes Indiana State Department of Health Laboratories Indianapolis, Indiana, USA	Janette Wassung PathCare Pathology Laboratory Cape Town, South Africa	Joanne P. Christopher <i>Assistant Editor</i>
John R. Harbour, MD, FCAP Bon Secours St. Mary’s Hospital Richmond, Virginia, USA		

Acknowledgment

CLSI and the Consensus Committee on Quality Systems and Laboratory Practices gratefully acknowledge the following individuals for their help in preparing this document:

Lisa A. Selhorst, BS, MT(AMT)
Blanchard Valley Hospital
Findlay, Ohio, USA

Peggy J. Stupca, MS, CLSp(CG)
Mayo Clinic (retired)
Rochester, Minnesota, USA

Contents

.....

Abstract	i
Committee Membership	iii
Foreword	viii
Chapter 1: Introduction	1
1.1 Scope	2
1.2 Background	2
1.3 Terminology	3
Chapter 2: Rationale for a Laboratory Internal Audit Program	9
2.1 Purpose and Goals of the Laboratory Internal Audit Program	10
2.2 Benefits of the Laboratory Internal Audit Program	10
2.3 Justification for an Internal Audit Program	11
Chapter 3: Development of the Laboratory Internal Audit Program	15
3.1 Structure of the Internal Audit Program	16
3.2 Defining Roles and Responsibilities	17
3.3 Designing the Audit Program	22
Chapter 4: Structure of the Internal Audit Process	27
4.1 The Auditing Process	28
4.2 Preparing for the Audit	29
4.3 Conducting the Audit	33
4.4 Evaluating the Effectiveness of the Audit Program	42
Chapter 5: Conclusion	45

.....

Contents (Continued)

.....

Chapter 6: Supplemental Information	47
References	48
Appendix A1. Laboratory Internal Auditor Training Guide	50
Appendix A2. Laboratory Internal Audit Trainer Responsibilities	51
Appendix A3. Laboratory Internal Auditing Learner Responsibilities.....	52
Appendix A4. Training Checklist for the Laboratory Internal Auditing Process	53
Appendix B. Annual Audit Schedule	54
Appendix C. Laboratory Internal Audit Plan.....	55
Appendix D. Example (Excerpt) of an Abbreviated Internal Audit Tool	56
Appendix E. Sample Laboratory Product Management Audit.....	57
Appendix F. Sample Audit Sheet	59
Appendix G1. Assessment Tool for Verifying the Effectiveness of Document Control (Format 1)	60
Appendix G2. Assessment Tool for Verifying the Effectiveness of Document Control (Format 2)	64
Appendix H1. Example of an Audit Findings Report.....	65
Appendix H2. Sample Audit Report.....	69
Appendix H3. Example of a Quality Assessment Audit Findings Report.....	71
Appendix H4. Assessment Findings and Quality Action Form	73
Appendix I. Audit Evaluation Example.....	74
Appendix J. Sample Internal Audit Feedback Form.....	75
The Quality Management System Approach	78
Related CLSI Reference Materials	80

This is a preview of "CLSI QMS15-A". [Click here to purchase the full version from the ANSI store.](#)



Foreword

NOTE:

The word **“audit”** should not be used interchangeably with the terms assessment, inspection, or survey, as they are **not the same thing!**

In the QMS, Assessments is one of the 12 quality system essentials (QSEs) described in CLSI document QMS01,¹ which defines a structured approach to organizing, creating, and maintaining the necessary information for the QSEs. The QMS model depicted in Figure 1 demonstrates how each QSE, including Assessments, is a building block to quality and necessary to support any laboratory’s path of workflow from preexamination to examination to postexamination.

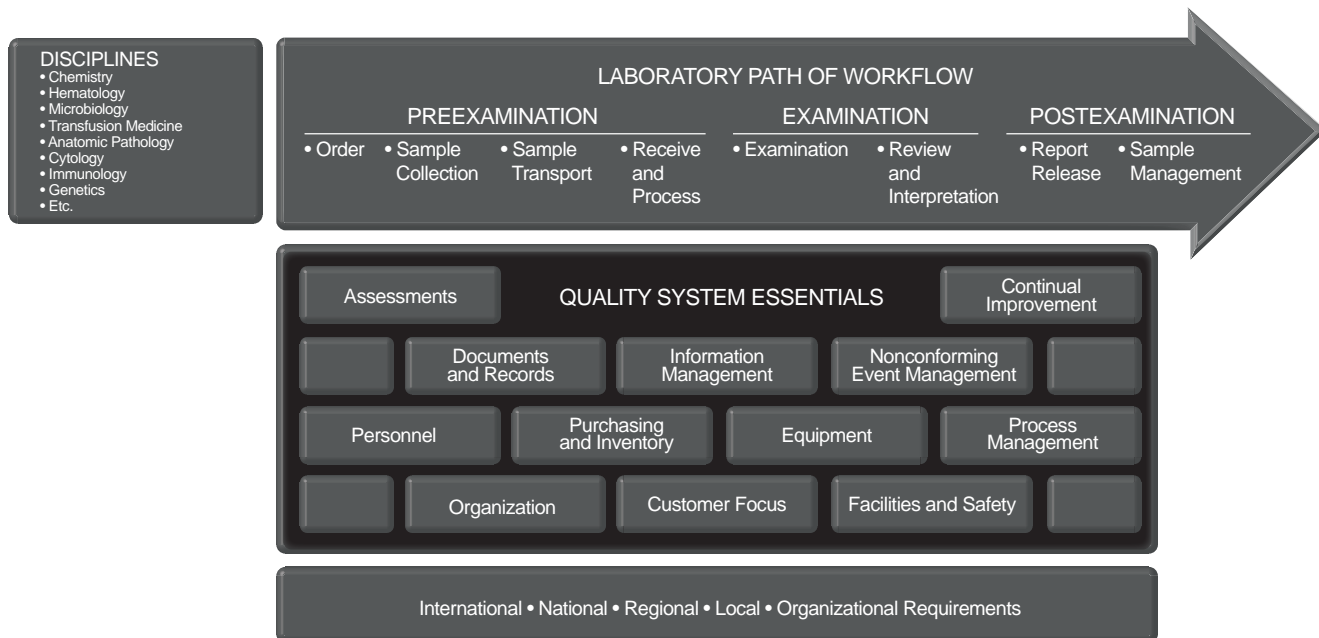


Figure 1. The Quality Management System Model (see CLSI document QMS01)¹

A laboratory audit program is critical to ensuring the laboratory meets applicable requirements. QSE Assessments encompasses both internal and external assessments, with separate elements for each (see Figure 2). This document provides guidance for implementing an internal audit program.

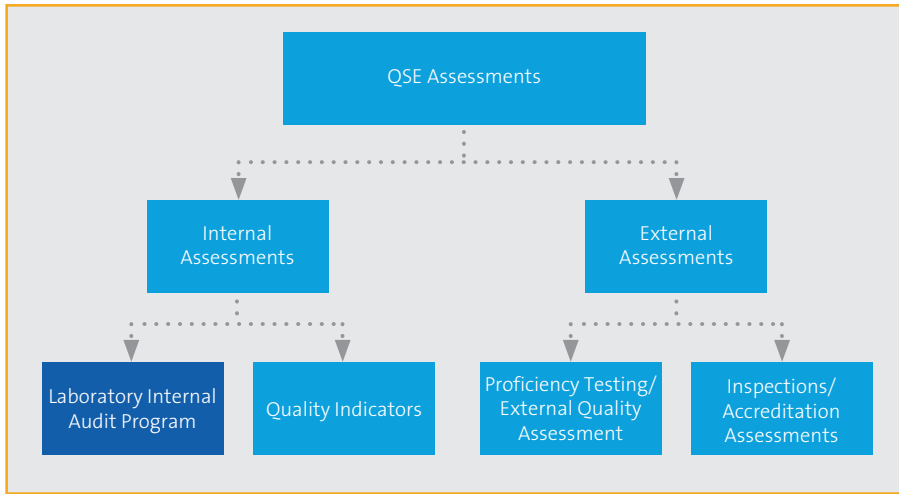


Figure 2. Components of QSE Assessments

KEY WORDS

- Assessment
- Audit
- Audit program
- Inspection
- Internal audit
- Quality management system

This is a preview of "CLSI QMS15-A". Click here to purchase the full version from the ANSI store.

.....

Chapter 1

Introduction

This chapter includes:

- ▶ Document scope and applicable exclusions
- ▶ Background information pertinent to the document content
- ▶ Standard Precautions information, as applicable
- ▶ Terms and definitions used in the document
- ▶ “Note on Terminology” that highlights particular use and/or variation in use of terms and/or definitions, where applicable
- ▶ Abbreviations and acronyms used in the document



Assessments: Laboratory Internal Audit Program; Approved Guideline

NOTE:

Internal audits of laboratory processes **provide objective evidence of nonconformances and risks** that can affect the quality of laboratory services and patient safety.

IMPORTANT NOTE:

The laboratory internal audit **program** described in this guideline is **scalable to any size laboratory**.

1 Introduction

1.1 Scope

This guideline is intended for use by laboratory leaders such as directors, managers, and supervisors, and other individuals associated with laboratories that perform medical testing. This document focuses on using a laboratory internal audit program to actualize the laboratory's commitment to quality, good professional practice, and continual improvement, by identifying problematic processes.

The examples provided are applicable to laboratories of any size and functional complexity. Some examples provided in both the text and the appendixes are not intended to be complete, but rather are abbreviated to clarify the material being presented.

1.2 Background

Internal auditing of work practices is an important QMS tool that helps a laboratory meet regulatory, accreditation, and customer requirements. Internal audits of laboratory samples, documents, and records provide objective evidence of nonconformances and risks that can affect the quality of laboratory services and patient safety. The identified nonconformances improve laboratory services through corrective actions while the identified risks provide opportunities for improvement. Internal audit programs can also identify positive practices that can be replicated within the laboratory environment and affirm compliance with requirements.

This guideline has adapted successful models used in business and industry and made them applicable to medical laboratories. It describes the use of an internal audit program and related processes for achieving enhanced quality and continual improvement in the clinical laboratory. An internal audit program and related processes are scalable to any size laboratory and require only the laboratory leadership's and staff's willingness to compare current practice to expectations.

The audit **program** defines the "who," "what," "when," "where," and "how" of meeting requirements for internal auditing, and the audit **process** describes the details of how to conduct individual laboratory internal audits. Committed laboratory leadership and individuals willing to share their expertise and experience will enable a successful internal audit program.